

CERTIFICATE OF ANALYSIS	CRP-LATEX
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REF

2410005	50 tests	X	2410020	100 tests (w/o control)	X	2410081 (1 L)	X	2924181 (100 mL)	
2410010	100 tests	X	2410027	150 tests (w/o control)	X	2410082 (0.25 L)	X	2924182 (50 mL)	
2410030	150 tests	X				2410085 (5 L)	X	2924185 (1 L)	

Cont	R	X
	Control (+)	X
	Control (-)	X

LOT	24133
	2-8°C

	2020-10
IVD	

PHYSICAL AND CHEMICAL CHARACTERISTICS

REAGENT	TEST	SPECIFICATIONS	RESULTS
CRP-LATEX (R)	APPEARANCE	Homogeneous suspension free of macroscopic or flaky particles.	ACCEPTED
	COLOUR	White	
	pH	9.5 +/- 0.2	
CONTROL (+)	APPEARANCE	Liquid solution. Clear and transparent.	ACCEPTED
CONTROL (-)	APPEARANCE	Liquid solution. Clear and transparent.	ACCEPTED

(ACCEPTED / N/A)

FUNCTIONALITY

REAGENT	TEST	SPECIFICATIONS	RESULTS
CRP-LATEX (R)	Sensitivity, against Reference Material CRM 470/RPPHS (Institute for Reference Materials and Measurements, IRMM)	6 (5-10) mg/L	ACCEPTED
	Positive Control	3+	
	Negative Control	Negative	
CONTROL (+)	Tested with CRP-Latex	3+	ACCEPTED
CONTROL (-)	Tested with CRP-Latex	Negative	ACCEPTED

(ACCEPTED / N/A)

STABILITY TEST (14 days at 37°C)

REAGENT	TOLERANCE	RESULT
CRP-LATEX	After a stability study, the specifications remain unchanged	ACCEPTED
CONTROL (+)		ACCEPTED
CONTROL (-)		ACCEPTED

(ACCEPTED / N/A)

Components from human origin have been tested and found negative for the presence of antibody to HIV (1/2) as well as HBsAg and HCV. However, handle cautiously as potentially infectious.

This lot was tested by test methods described in the manufacturer's package insert. These results are applicable to this lot and sequential sublots, for which a capital letter have been assigned after the lot number.

This Certificate of Analysis is a computer printout and has therefore not been signed by hand.

This lot meets our specifications and is released for sale	APPROVED	Signed Date of Manufacture: Aina Iglesias 2018-03-22 Quality Control Dept.
	(APPROVED / NOT APPROVED)	

